

Appl. No10/757,093
Amdt. dated 24 August 2005
Reply to Office Action of 25 April 2005

Amendments to the Drawings:

Figures 10A and 10B are amended to remove the brief description. Attached to this amendment are new sheets 30 and 31 as well as original sheets 30 and 31 showing the changes.

REMARKS

Reconsideration of this Application is respectfully requested. Claims 1-5 and 7-30 are pending; claim 6 is canceled without prejudice; claims 1, 2, 8, 9, and 29 are currently amended; claims 3-5, 7, 10-28, and 30 are original. The Remarks below are directed to the objections and rejections of the outstanding Office Action.

Remarks to Objections to the Specification

(A) The disclosure was objected to because it contained hyperlinks. Amendments to the specification have removed the hyperlinks.

(B) The drawings were objected to because Figures 10A and B are too dark and "no details can be made out". The original photographs that were used to make Figures 10A and B were in color; when printed in black and white, maximum contrast was strived for in order to preserve detail and discrimination of the colors. The drawings as submitted are believed to have sufficient detail and tonal qualities. As such, the Office is requested to drop the rejection. If however, the Office continues to maintain the objection, it is requested that particularity be provided so that the Assignee understands what type of detail is believed to be lacking.

(C) Figures 10A and B were objected to because of extraneous wording on the sheets of figures. These figures have been amended to remove the objectionable words. A clean set of figures as well as a marked-up set are attached to this amendment.

In light of the amendments and remarks aabove , the Office is respectfully requested to remove the objections.

Remarks to Objections to the Claims

(A) Claims 1, 9, 19-27, 29, and 30 were objected to because of an incorrect nucleotide numbering with respect to SEQ ID NO: 3. The error arose because the nucleotide numbering originally referred to numbering in the Figures instead of the SEQ ID listing. The claims have now been amended to correct the nucleotide numbering so that it refers to the nucleotide sequence of SEQ ID NO: 3.

(B) Claims 1, 2, 8, 9, 19-27, 29 and 30 were objected to for reciting non-elected SEQ ID NOs. The claims have been amended to remove non-elected SEQ ID NOs.

(C) Claim 29 was objected to for a spelling error. This error has been fixed

by amendment.

In light of the amendments and remarks above, the Office is respectfully requested to remove the objections.

Remarks to Claim Rejections under 35 USC § 112, paragraph 1

(A) The Office rejected claims 1-5 and 7-30 as failing to comply with the written description requirement. In essence, the Office contends that Applicant does not describe a nucleic acid molecule encoding a fungal β -glucuronidase or a fungal β -glucuronidase other than SEQ ID NO: 3 and SEQ ID NO: 4.

This rejection is respectfully traversed. The written description requirement does not require that each and every species of a genus be disclosed to the level of its primary nucleotide or amino acid sequence. The proper test for adequate written description is whether one of skill in the art would understand, from reading the description, whether the inventors had possession of the subject matter of the claims. One of skill in the art can distinguish the claimed sequences from any other sequence and can identify many, if not all, of the species that the claims encompass. Thus, the claims satisfy the written description requirement as enunciated in *Eli Lilly*. Specifically, the genus in the claims are very well defined in that all of the proteins encompassed by the claimed genus are well-defined as specifically enumerated β -glucuronidases. The several examples of fungal β -glucuronidases taught in the specification demonstrate that the Applicant had possession of the class of genres claimed. It is with resignation therefore, in order to advance prosecution, that the claims have been amended to recite the specific sequences: SEQ ID NOs: 3 and 4.

(B) In addition, the Office rejected claims 1-5 and 7-30 for lack of enablement, in essence, asserting that the specification is not enabled for molecules other than the specific fungal β -glucuronidase exemplified by SEQ ID Nos: 3 and 4. To bolster its rejection, the Office cites several references that ostensibly show the unpredictability of product function after making nucleotide substitutions in the encoding gene.

This rejection is also respectfully traversed. First, the Office postulates that there is unpredictability of function of mutated proteins; however, the references that the Office cites at most pertain to the three proteins that are the subject of the experiments: growth factor alpha, ADP-glucose pyrophosphorylase and 3-methyladenine DNA

glycosylase. The proteins of the cited references bear no similarity in structure or function to β -glucuronidase. Assuming, for the moment, that the references show that the function of the mutated protein is unpredictable, these references lack any demonstrated relationship to the protein of the instant invention. Moreover, the Office cites these references in the general sense and has not pointed to any particular part of these references as supporting the current rejection of fungal β -glucuronidases.

Second, the Office argues that the specification does not provide adequate guidance to make the claimed substitutions. The underlying gist of this contention appears to be that the specification lacks working examples using sequences that are related by hybridization or by sequence identity to SEQ ID NOS: 3 or 4. With respect to the Office, the presence or absence of working examples, however, is not the touchstone of enablement. Patent law only requires that the specification sufficiently enable any person skilled in the art to make and use the invention. This, the specification does -- through its teaching of how to make the related sequences, how to screen for those molecules exhibiting functional activity and how to use them.

Third, the Office states, but does not explain how, undue experimentation would be necessary to develop and evaluate the claimed molecules. The Office apparently makes this conclusion based on combinatorial factoring of possible changes. Yet, the "test of undue experimentation is not merely quantitative, since a considerable amount of experimentation is permissible, *if it is merely routine...*" (*In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988); emphasis added). Yet, the argument of the Office is one of quantitation; it has failed to explain how the experimentation needed is anything other than routine. For these reasons, the Office has not made a case of lack of enablement.

While disagreeing with the Office's rejection and reasoning, the amendments made to further the prosecution of this application will have obviated the rejections for lack of enablement and lack of written description. Therefore, the Office is kindly requested to remove these rejections.

Remarks to Claim Rejection under 35 USC § 112, paragraph 2

(A) Claim 2 was rejected for indefiniteness of the phrase "encodes one of the amino acid sequences SEQ ID NO: 2, 4, residues 19-634 of SEQ ID NO:4." SEQ ID NO: 2 has been deleted and the phrase amended to read "encodes SEQ ID No: 4 or encodes

residues 19-634 of SEQ ID NO:4". This amendment clarifies that the nucleic acid sequence encodes either SEQ ID NO:4 (β -glucuronidase with signal peptide) or residues 19-634 of SEQ ID NO:4 (β -glucuronidase without signal peptide).

(B) Claim 25 was rejected for lack of antecedent basis for the phrase "compound is an auxin or a hormone". The phrase has been amended to recite "aglycone is an auxin or a hormone"; claim 21 recites an aglycone, thus there is now proper antecedent basis.

(C) Claim 29 (the OA states claim 9, but it is claim 29 that contains the term) was rejected for the indefinite term "controller element". The term has been amended to "regulatory sequence". Support for this term is found in e.g., paragraph 0082.

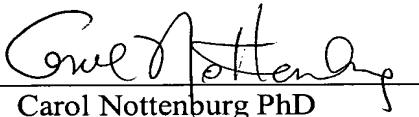
All claim rejections have been obviated by amendment; the Office is thus kindly requested to remove these rejections.

Conclusion

We respectfully request that the Examiner reconsider the noted outstanding Office Action and that the objections and rejections be withdrawn. Assignee believes that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Respectfully submitted,

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30/31

~~β -glucuronidase activity in leaves of rice T1 plants
transformed with pPWT9.17~~

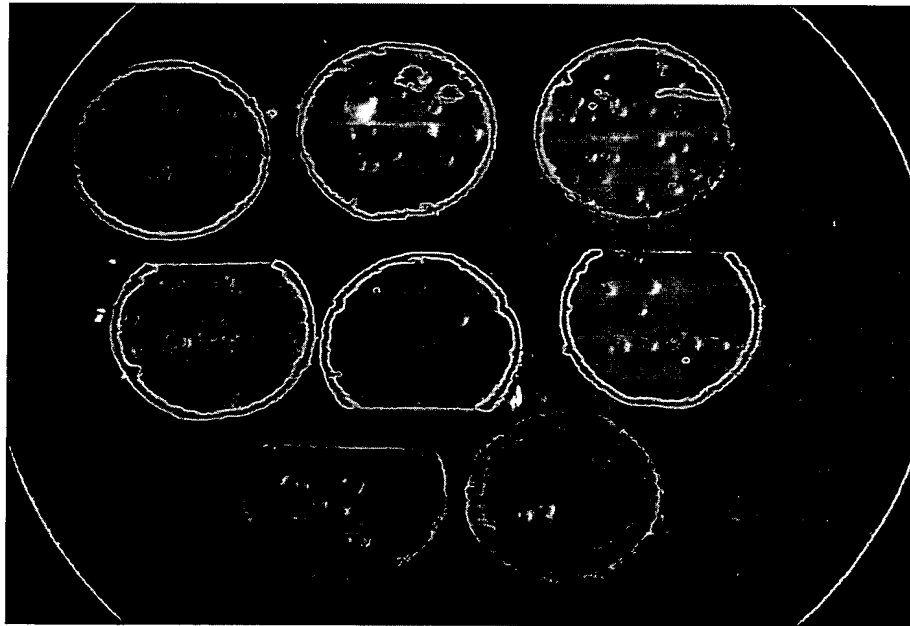


FIG.10A

~~— Secreted β -glucuronidase activity in leaves of rice T1~~
~~— plants transformed with pKKWA68.4 and pPWT9.17~~

pCAMBIA1305.2

pKKWA68.4

pPWT9.17

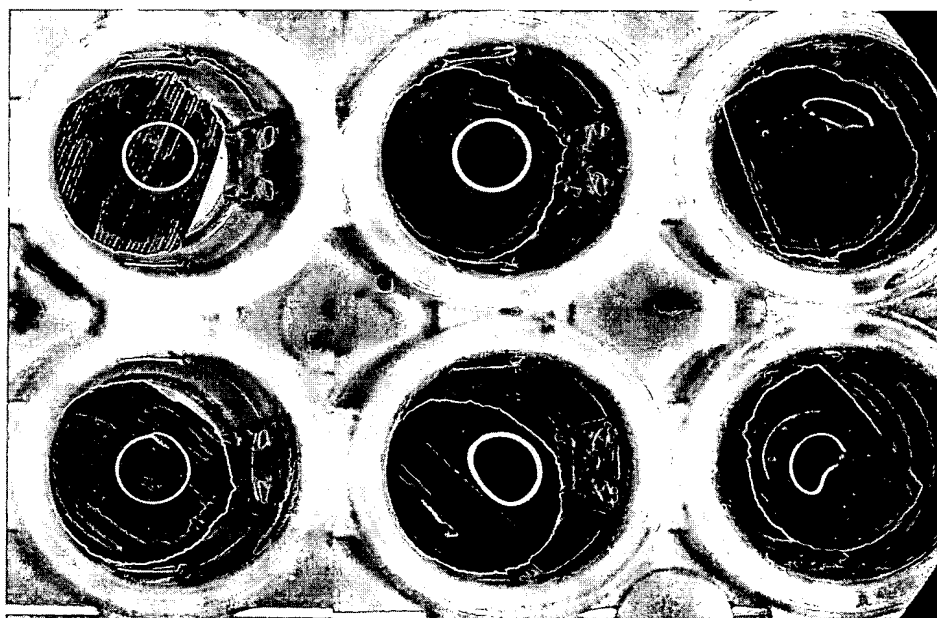


FIG.10B